

**ROBITUSSIN PEAK COLD COUGH PLUS CHEST CONGESTION DM- dextromethorphan hydrobromide and guaifenesin solution**  
**ROBITUSSIN PEAK COLD SUGAR-FREE COUGH PLUS CHEST CONGESTION DM- dextromethorphan hydrobromide and guaifenesin solution**  
**Richmond Division of Wyeth**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Robitussin® Peak Cold Cough+Chest Congestion DM**  
**Robitussin® Peak Cold Sugar-Free Cough+Chest Congestion DM**  
**(dextromethorphan HBr, guaifenesin)**

***Drug Facts***

<b><i>Active ingredients</i></b> <b><i>(in each 10 ml)</i></b>	<b><i>Purposes</i></b>
Dextromethorphan HBr, USP 20 mg	Cough suppressant
Guaifenesin, USP 200 mg	Expectorant

***Uses***

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

***Warnings***

**Do not use** if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

**Ask a doctor before use if you have**

- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema

**Stop use and ask a doctor if** cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

***Directions***

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- keep dosing cup with product
- ml = milliliter
- this adult product is not intended for use in children under 12 years of age

<b>age</b>	<b>dose</b>
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adults and children 12 years and over	10 ml every 4 hours
children under 12 years	do not use

### ***Other information***

#### **Robitussin Peak Cold Cough+Chest Congestion DM**

- **each 10 ml contains:** sodium 7 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

#### **Robitussin Peak Cold Sugar-Free Cough+Chest Congestion DM**

- **each 10 ml contains:** sodium 5 mg
- store at 20-25°C (68-77°F). Do not refrigerate.
- alcohol-free

### ***Inactive ingredients***

#### **Robitussin Peak Cold Cough+Chest Congestion DM**

anhydrous citric acid, FD&C red no. 40, glycerin, high fructose corn syrup, menthol, natural flavor, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sucralose

#### **Robitussin Peak Cold Sugar-Free Cough+Chest Congestion DM**

acesulfame potassium, artificial & natural flavor, citric acid monohydrate, glycerin, methylparaben, polyethylene glycol, povidone, propylene glycol, purified water, saccharin sodium, sodium benzoate

### ***Questions or comments?***

call weekdays from 9 AM to 5 PM EST at **1-800-762-4675**

For most recent product information, **visit [www.robitussin.com](http://www.robitussin.com)**

Distributed by:

Pfizer, Madison, NJ 07940 USA

### **PRINCIPAL DISPLAY PANEL - 118 ml Bottle Carton**

#### **ADULT**

**Robitussin®**

**PEAK COLD**

**Cough+Chest  
Congestion DM**

**DEXTROMETHORPHAN HBr (Cough Suppressant)**

**GUAIFENESIN (Expectorant)**

**Relieves:**

- Cough
- Mucus

**Non-Drowsy DM**

For Ages 12 & Over

4 FL OZ

(118 ml)

ADULT

**Robitussin**

PEAK COLD

Cough+Chest  
Congestion **DM**

**DM**

ADULT

**Robitussin**

PEAK COLD

Cough+Chest  
Congestion **DM**

DEXTROMETHORPHAN HBr (Cough Suppressant)  
GUAIFENESIN (Expectorant)

**Relieves:**

- ✓ Cough
- ✓ Mucus

**Non-Drowsy**

**DM**

Robitussin® liquid formula **provides soothing action and targets the source of your cough** – plus relieves your chest congestion.

ADULT

**Robitussin**

PEAK

Cough+Chest  
Congestion **DM**

DEXTROMETHORPHAN HBr (Cough Suppressant)  
GUAIFENESIN (Expectorant)

Should be 18 or older to purchase

**PARENTS:**

Learn about teen medicine abuse

For Ages 12 & Over

4 FL OZ  
(118 ml)

[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

LOT:  
EXP:

Do Not Use if breakable ring is separated or missing.  
Packaged with Tamper-Evident bottle cap.

ADULT

**Robitussin<sup>®</sup>**

PEAK COLD

**Cough+Chest  
Congestion DM**

#### Drug Facts

**Active ingredients  
(in each 10 ml)**

Dextromethorphan HBr, USP 20 mg .... Cough suppressant

**Purposes**

#### Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

#### Directions

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- keep dosing cup with product
- ml = milliliter
- this adult product is not intended for use in children under 12 years of age

age	dose
adults and children 12 years and over	10 ml every 4 hours
children under 12 years	do not use

#### Other information

- each 10 ml contains: sodium 7 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

**Inactive ingredients** anhydrous citric acid, FD&C red no. 40, glycerin, high fructose corn syrup,



## PRINCIPAL DISPLAY PANEL - 118 ml Sugar-Free Bottle Carton

**ADULT**

**Robitussin®**

**PEAK COLD**

**SUGAR-FREE**

**Cough+Chest  
Congestion DM**

**DEXTROMETHORPHAN HBr (Cough Suppressant)  
GUAIFENESIN (Expectorant)**

**Relieves:**

- Cough
- Mucus

**Specially  
Formulated**

**for DIABETICS**

**Non-Drowsy DM**  
**SUGAR-FREE**  
**DYE-FREE**

For Ages 12 & Over

4 FL OZ  
(118 ml)



ADULT

**Robitussin**

PEAK COLD

SUGAR-FREE

Cough+Chest  
Congestion **DM**

**DM**  
SUGAR-FREE  
DYE-FREE

ADULT

**Robitussin**

PEAK COLD

SUGAR-FREE

Cough+Chest  
Congestion **DM**

DEXTROMETHORPHAN HBr (Cough Suppressant)  
GUAIFENESIN (Expectorant)

**Relieves:**

- ✓ Cough
- ✓ Mucus

Specially  
Formulated  
for DIABETICS

**Non-Drowsy**

**DM**  
SUGAR-FREE  
DYE-FREE

Robitussin® liquid  
formula **provides**  
**soothing action**  
**and targets the**  
**source of your cough**  
– plus relieves your  
chest congestion.

ADULT

**Robitussin**

PEAK

SUGAR-FREE

Cough+Chest  
Congestion **DM**

DEXTROMETHORPHAN HBr (Cough Suppressant)  
GUAIFENESIN (Expectorant)

Should be 18 or older to purchase

**PARENTS:**

Learn about teen medicine abuse



For Ages 12 & Over

4 FL OZ  
(118 ml)

[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

LOT:  
EXP:

Packaged with Tamper-Evident bottle cap.  
Do Not Use if breakable ring is separated or missing.

ADULT

**Robitussin®**

PEAK COLD

SUGAR-FREE

**Cough+Chest  
Congestion DM**

#### Drug Facts

##### Active ingredients (in each 10 ml)

Dextromethorphan HBr, USP 20 mg .... Cough suppressant  
Guaifenesin, USP 200 mg ..... Expectorant

##### Purposes

#### Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

#### Directions

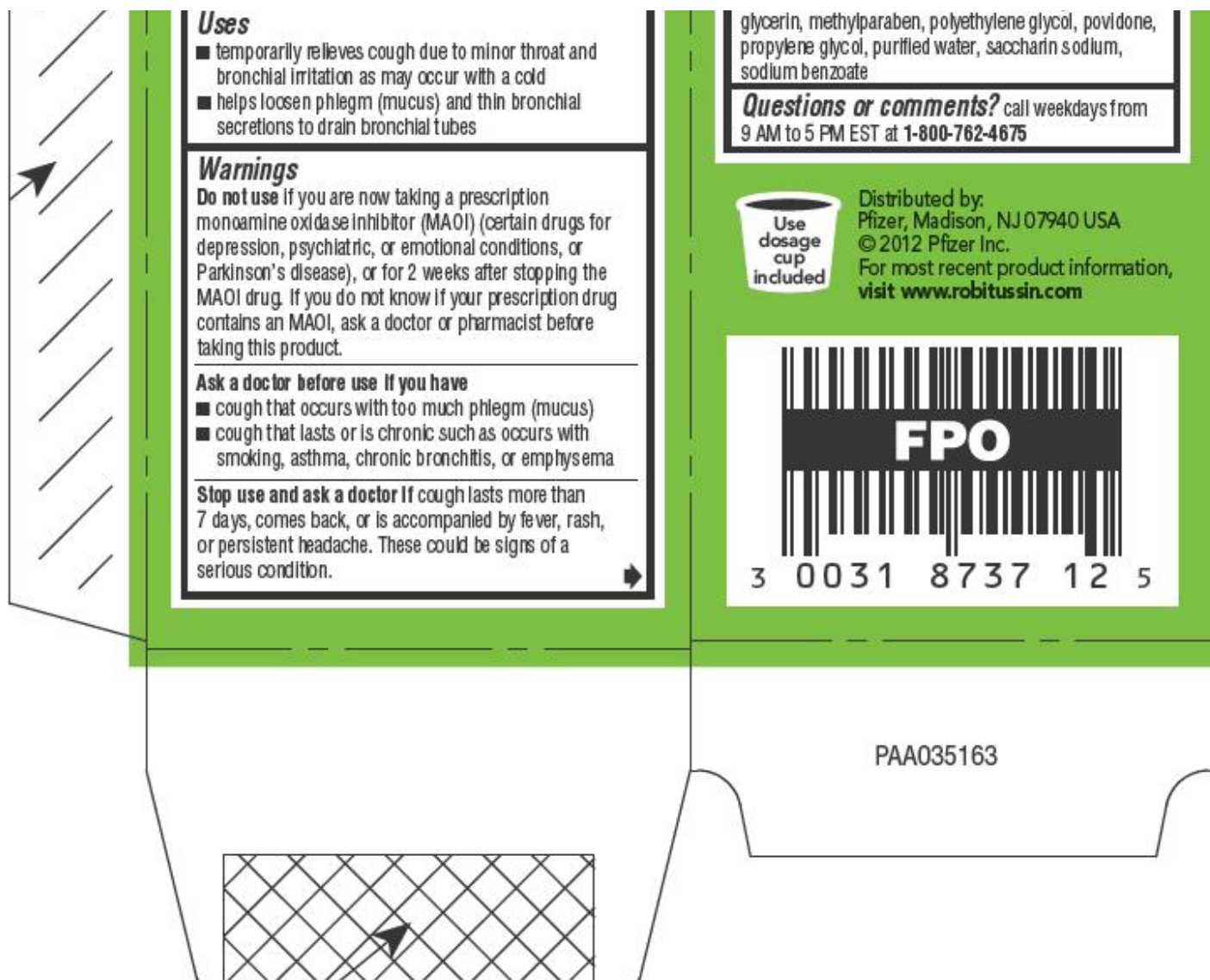
- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- keep dosing cup with product
- ml = milliliter
- this adult product is not intended for use in children under 12 years of age

age	dose
adults and children 12 years and over	10 ml every 4 hours
children under 12 years	do not use

#### Other information

- each 10 ml contains: sodium 5 mg
- store at 20-25°C (68-77°F). Do not refrigerate.
- alcohol-free

**Inactive ingredients** acesulfame potassium, artificial & natural flavor, citric acid monohydrate,



## ROBITUSSIN PEAK COLD COUGH PLUS CHEST CONGESTION DM

dextromethorphan hydrobromide and guaifenesin solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0031-8736
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
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ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	RED (clear red liquid)	Score	
Shape		Size	
Flavor	PINEAPPLE (pineapple orange flavor and odor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8736-12	1 in 1 CARTON	06/15/2011	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0031-8736-18	1 in 1 CARTON	06/15/2011	
2		237 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0031-8736-42	1 in 1 CARTON	06/15/2011	
3		355 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	06/15/2011	

ROBITUSSIN PEAK COLD SUGAR-FREE COUGH PLUS CHEST CONGESTION DM

dextromethorphan hydrobromide and guaifenesin solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0031-8737
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH)	DEXTROMETHORPHAN	10 mg

(DEXTROMETHORPHAN - UNII:7355X3ROTS)		HYDROBROMIDE	in 5 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)		GUAIFENESIN	100 mg in 5 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)				
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
GLYCERIN (UNII: PDC6A3C0OX)				
METHYL PARABEN (UNII: A2I8C7HI9T)				
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)				
POVIDONES (UNII: FZ989GH94E)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
WATER (UNII: 059QF0KO0R)				
Product Characteristics				
Color	YELLOW (clear colorless to slightly yellow liquid)	Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8737-12	1 in 1 CARTON	06/15/2011	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0031-8737-13	1 in 1 CARTON	06/15/2011	
2		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL		part341	06/15/2011	

**Labeler** - Richmond Division of Wyeth (829390835)

## Establishment

Name	Address	ID/FEI	Business Operations
Pfizer Canada Inc.		246770197	ANALYSIS(0031-8736) , LABEL(0031-8736) , MANUFACTURE(0031-8736) , PACK(0031-8736)